

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS [S0]**

Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:

VITAFEN® Multivitamin & Mineral Tablets

Each tablet contains:

Ingredients	Elemental value	NRV% *
Vitamin A (as Betacarotene)	1000.0 µg	125.0
Vitamin B1 (as Thiamine Hydrochloride)	13.1 mg	1092.6
Vitamin B2 (as Riboflavin)	14.7 mg	1130.8
Vitamin B3 (as Nicotinamide)	14.7 mg	91.9
Vitamin B5 (as Pantothenic Acid)	18.0 mg	359.0
Vitamin B6 (as Pyridoxine Hydrochloride)	16.1 mg	948.5
Vitamin B7 (as D-Biotin)	100.0 µg	333.3
Vitamin B9 (as Folic Acid)	200.0 µg	50.0
Vitamin B12 (as Cyanocobalamin)	4.0 µg	166.7
Vitamin C (as Ascorbic Acid)	58.2 mg	58.2
Vitamin D3 (as Cholecalciferol)	500.0 iu	83.3
Vitamin E (as DL-alpha-Tocopherol Acetate)	8.3 mg	55.1
Vitamin K2 (as Menaquinone)	60.0 µg	50.0
Calcium (as Dicalcium Phosphate)	88.4 mg	6.8
Chromium (as Chromium Picolinate)	94.6 µg	270.2
Copper (as Copper Sulphate Pentahydrate)	500.0 µg	55.5
Iodine (as Potassium Iodine)	137.5 µg	91.7
Iron (as Ferrous Fumarate)	6.9 mg	52.9
Magnesium (as Magnesium Oxide)	30.2 mg	8.3
Phosphorus (as Dicalcium Phosphate)	34.2 mg	2.7
Potassium (as Potassium Iodide)	40.0 µg	*
Selenium (as Selenium Amino Acid Chelate)	3.0 µg	5.5
Zinc (as Zinc Amino Acid Chelate)	5.0 mg	50.0
Citrus Bioflavonoid Extract 35%	30.0 mg	*
Citrus Aurantium L Extract (providing Hesperidin)	10.5 mg	
Ginseng Extract 5:1	50.0 mg	*
L-Glutamine	200.0 mg	*

(NRV) South African Nutrient reference values for individuals 4 years and older

*NRV not established.

Other ingredients:

Flexi-Coat® Orange Coating Agent, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Talc, Titanium Dioxide. Contains no artificial sweeteners or sugar.

PHARMACOLOGICAL CLASSIFICATION

34.12 Category D (Health Supplement) [S0]

INDICATIONS**Contributes to:**

- The maintenance of immune function, skin, nails, bones, hair, testosterone levels in the blood and vision.
- Normal acid-base metabolism, cognitive function, DNA synthesis, fertility & reproduction and macronutrient metabolism.
- The normal function of blood vessels, cartilage, bones, gums, skin and teeth.
- Normal functioning of the muscles.
- Normal energy-yielding metabolism, functioning of the nervous system, psychological function and normal growth.
- The protection of cells from oxidative stress, free radical damage and connective tissue formation,
- Iron absorption from food.
- The development and maintenance of strong bones and teeth, eyesight, skin, membranes and immune system functions.
- Normal cell division and blood calcium levels.
- The normal production of thyroid hormones and thyroid function.
- Metabolising carbohydrates, fats and proteins in the body.
- Forming and functioning of red blood cells.
- The production and repair of connective tissue.
- Source of L-Glutamine (Amino Acid) involved in muscle protein synthesis.

Has a role in the process of cell division.

A factor in the maintenance of good health.

Helps in the absorption and use of calcium & phosphorus.

Source of antioxidants that helps protect cells from the effects of oxidative damage.

Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis.

"A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance."

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients. If you are pregnant or breastfeeding your baby or following, please consult your health care provider for advice before taking this medicine.

WARNINGS AND SPECIAL PRECAUTIONS

Do not exceed the recommended dose. Follow all directions on your medicine label. Always tell your healthcare provider if you are taking any other medicine. If you are taking prescription medication or following a low-protein diet, please consult your health care provider for advice before taking this medicine. People with chronic conditions should use this product with caution as Ginseng may influence the condition.

An overdose of vitamins A, D or E can cause serious or life-threatening side effects if taken in large doses.

Certain minerals may also cause serious overdose symptoms if you take too much.

Not recommended for children under the age of 18 years, unless under medical supervision.

KEEP OUT OF REACH OF CHILDREN.**INTERACTIONS**

Vitamin and mineral supplements can interact with certain medications, or affect how medications work in your body.

Ask a doctor or pharmacist before using multivitamins and minerals with any other medications, especially with:

- Acne treatment medication, antacids, antibiotics, anticoagulants, antiepileptics, diuretics "water pills"; heart or blood pressure medications, thyroid medication and anti-inflammatory medicine.

Always consult your healthcare professional if you are taking any other drugs before taking this medicine.

DOSAGE AND DIRECTIONS FOR USE

Adults: Take 1 tablet per day with a glass of water, after a meal.

Do not share medicines prescribed for you with any other person. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE EFFECTS

Signs of an allergic reaction are:

- Rash, hives and itching.
- red, swollen, blistered, or peeling skin with or without fever.
- Wheezing, tightness in the chest or throat, trouble breathing, swallowing or talking and unusual hoarseness.
- Swelling of the mouth, face, lips, tongue, or throat.

- Upset stomach or throwing up.
- Headaches.
- Unusual or unpleasant taste in the mouth.

Minerals (especially taken in large doses) can cause side effects such as:

- Tooth staining.
- Increased urination.
- Stomach bleeding.
- Uneven heart rate.
- Confusion.
- Muscle weakness.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any side effects while taking this medicine, please consult your health care provider for advice.

STORAGE INSTRUCTIONS

Close the container properly after usage. Store in a cool, dry place below 25 °C. Do not leave the container open or store it in a fridge.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION

White with White lid packaged container with tamperproof induction seal, a sponge and a silica gel sachet. Clearly labelled with detailed information printed on the label. Containing 30 or 60 tablets.

IDENTIFICATION

Orange-coated oblong tablets.

REGISTRATION NUMBER

To be allocated.

APPLICANT

Pharmafen (Pty) Ltd
449, 34th Avenue, Villieria
Pretoria, 0186, South Africa
Email: info@pharmafen.co.za
Website: www.pharmafen.co.za

® = Registered trademark

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

September 2022

Complementary Medicine: Health Supplement

Classification D (HS)

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

PASIËNT INLIGTINGSBLAADJIE

SKEDULERINGSSTATUS [S0]

Nie geskeduleer nie

HANDELSNAAM EN DOSERINGSVORM:

VITAFEN® Multivitamien & Minerale Tablette

Elke tablet bevat:

Bestanddele	Elementêre waarde	NRV% *
Vitamiën A (as Betakaroteen)	1000.0 µg	125.0
Vitamiën B1 (as Tiamienhidrochloried)	13.1 mg	1092.6
Vitamiën B2 (as Riboflavin)	14.7 mg	1130.8
Vitamiën B3 (as Nikotinamied)	14.7 mg	91.9
Vitamiën B5 (as Pantoteensuur)	18.0 mg	359.0
Vitamiën B6 (as Piridoksienhidrochloried)	16.1 mg	948.5
Vitamiën B7 (as D-Biotien)	100.0 µg	333.3
Vitamiën B9 (as Foliensuur)	200.0 µg	50.0
Vitamiën B12 (as Sianokobalamien)	4.0 µg	166.7
Vitamiën C (as Askorbiensuur)	58.2 mg	58.2
Vitamiën D3 (as Cholecalciferol)	500.0 iu	83.3
Vitamiën E (as DL-alfa-Tokoferol Asetaat)	8.3 mg	55.1
Vitamiën K2 (as Menakinoon)	60.0 µg	50.0
Kalsium (as Dikalsiumfosfaat)	88.4 mg	6.8
Chroom (as Chroompikolinaat)	94.6 µg	270.2
Koper (as Kopersulfaatpentahidraat)	500.0 µg	55.5
Jodium (as Kaliumjodied)	137.5 µg	91.7
Yster (as Ysterfumaaraat)	6.9 mg	52.9
Magnesium (as Magnesiumoksied)	30.2 mg	8.3
Fosfaat (as Dikalsiumfosfaat)	34.2 mg	2.7
Kalium (as Kaliumjodied)	40.0 µg	*
Selenium (as Selenium Aminosuurchelaat)	3.0 µg	5.5
Sink (as Sink Aminosuurchelaat)	5.0 mg	50.0
Sitrus bioflavanoïed Ekstrak 35%	30.0 mg	*
Sitrus Aurantium L Ekstrak (voorsien Hesperidien)	10.5 mg	*
Ginseng Ekstrak 5:1	50.0 mg	*
L-Glutamien	200.0 mg	*

(NRV) Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer.

*NRV nie vasgestel nie.

Ander bestanddele:

Flexi-Coat® Oranje Deklaag Agent, Magnesiumstearaat, Mikrokristallyne Sellulose, Povidoon, Talk, Titaandioksied. Bevat geen suiker of kunsmatige versoeter.

FARMAKOLOGIESE KLASSIFIKASIE

34.12 Kategorie D (Gesondheidsaanvuller) [S0]

INDIKASIES

Dra by tot:

- Die handhawing van immuunfunksie, vel, naels, bene, hare, testosteroonvlakke in die bloed en visie.
- Normale suur-basis metabolisme, kognitiewe funksie, DNA sintese, vrugbaarheid en voortplanting en makrovoedingstof metabolisme.
- Die normale funksionering van bloedvate, kraakbeen, bene, tandvleis, vel en tande.
- Normale funksionering van die spiere.
- Normale energie-oplewende metabolisme, funksionering van die sensuïesisteme, psigologiese funksie en normale groei.
- Die beskerming van selle teen oksidatiewe stres, vrye radikale skade en bindweefselvorming,
- Ysterabsorpsie vanuit voedsel.
- Die ontwikkeling en instandhouding van sterk bene en tande, sig, vel, membrane en immuunselfunksies.
- Normale seldeling en bloedkalsiumvlakke.
- Die normale produksie van tiroïedhormone en tiroïedfunksie.
- Metabolisering van koolhidrate, vette en proteïene in die liggaam.
- Vorming en funksionering van rooibloedselle.
- Die produksie en herstel van bindweefsel.
- Bron van L-Glutamien (Aminosuur) betrokke by spierproteïensintese.

Speel 'n rol in die proses van seldeling.

'n Faktor in die handhawing van goeie gesondheid.

Help met die opname en gebruik van kalsium en fosfor.

Bron van antioksidante wat help om selle teen die effekte van oksidatiewe skade te beskerm.

Kalsium inname, gekombineer met voldoende vitamien D, asook 'n gesonde dieet en gereelde oefening, kan die risiko van osteoporose verminder.

“'n Omvattende en gebalanseerde eetplan is die mees doeltreffende- en veiligste manier vir die handhawing van goeie gesondheid om geestelike en fisiese doelwitte te bereik.”

KONTRA-INDIKASIES

Hipersensitiwiteit vir enige van die bestanddele. Indien swanger of borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat hierdie medisyne gebruik word.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Moenie die aanbevole dosis oorskry nie. Volg alle aanwysings op jou medisyne-etiket. Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. As jy voorskryfmedikasie neem of 'n lae-proteïen dieet volg, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem. Mense met kroniese toestande moet hierdie produk met omsigtigheid gebruik word aangesien Ginseng die toestand kan beïnvloed. 'n Oordosis van vitamien A, D of E kan ernstige of lewensgevaarlike nuwe-effekte veroorsaak as dit in groot dosisse geneem word. Sekere minerale kan ook ernstige oordosis simptome veroorsaak as jy te veel inneem.

Nie aanbeveel vir kinders onder die ouderdom van 18 jaar nie, tensy onder mediese toesig.

HOU BUITE BEREIK VAN KINDERS.

INTERAKSIES

Vitamiën- en mineraalaanvullings kan interaksies met sekere medikasie hê, of beïnvloed hoe medikasie in jou liggaam werk. Vra 'n dokter of apteker voordat multivitamiene en minerale saam met enige ander medikasie gebruik word, veral met:

- Aknee-behandeling medikasie, teensuurmiddels, antibiotika, antikoagulant, anti-epileptika, diuretika "water pille"; hart- of bloeddrukmedikasie, skildkliermedikasie en anti-inflammatoriese medisyne.

Raadpleeg altyd u gesondheidswerker as u enige ander middels gebruik voordat u hierdie medisyne gebruik.

DOSERING EN GEBRUIKSAANWYSINGS:

Volwassene: Neem 1 tablet daaglik, met 'n glas water na 'n maaltyd.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

NEWE-EFFEKTE

Tekens van 'n allergiese reaksie is:

- Uitslag, jeukerigheid, rooi-, geswelde-, blase of afskilferende vel met of sonder koors.
- Benoudheid in die bors of keel, probleme met asemhaling, sluk of praat en ongewone heesheid.
- Swelling van die mond, gesig, lippe, tong of keel.

- Maagontsteldheid of braking.
- Hoofpyne.
- Ongewone of onaangename smaak in die mond.

Minerale (veral in hoë dosisse) kan newe-effekte veroorsaak soos:

- Tandvlekke.
- Verhoogde urinering.
- Maagbloeding.
- Onreelmatige hartklop.
- Verwarring.
- Spierswakheid.

Nie alle newe-effekte is in hierdie pamflet gelys nie. Indien u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar, raadpleeg u gesondheidsorgverskaffer vir advies.

BERGINGSINSTRUKSIES

Verseël die houer behoorlik na gebruik. Bêre op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat of in die yskas bêre nie.

STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

AANBIEDING

Wit met Wit deksel verpakte houer met peuterbestande induksie seël, 'n spons en 'n silikagel sakkie. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 30 of 60 tablette.

IDENTIFIKASIE

Oranje bedekte langwerpige tablette.

REGISTRASIE NOMMER

Om toegeken te word.

AANSOEKER

Pharmafen (Pty) Ltd
449, 34^{ste} Laan, Villieria
Pretoria, 0186, Suid-Afrika
E-pos: info@pharmafen.co.za
Webwerf: www.pharmafen.co.za

® = Geregistreerde handelsmerk

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET

September 2022

Aanvullende Medisyne: Gesondheidsaanvuller

Klassifikasie: D (HS)

Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnose, behandeling, genesing of voorkoming van enige siekte nie.